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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,909	12/27/2003	John H. Shadduck	S-AI-00100	7435

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John H. Shadduck
1490 Vistazo West
Tiburon, CA 94920

EXAMINER	
MENDEZ, MANUEL A	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,909	SHADDUCK, JOHN H.	
	Examiner	Art Unit	
	Manuel Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by **Ellinwood, Jr., Garay et al, and Orth et al.**

The Ellinwood, Jr., patent discloses an implantable agent release body carrying at least one pharmacologically active agent and implanting the agent release body in a targeted site within the gastrointestinal tract. This assertion of fact has its origin in column 4 lines 30-44, wherein the specification states "Involved in the biological sensing for blood pressure or other physiological changes that the device is evaluating, are possible training of physiological responses, effects or behavioral modification effects, by means of appropriate programming of such a device with small logic circuits. The type of signal detected and used for processing in the logic circuits may be either one signal or a combination of bio-signals, one or several being necessary for the triggering of the later described pump-dispensing device. For example, by implanting an appropriate device in drug addicts one may monitor a variety of physiological changes produced by the injection of a narcotic; that is, respiratory depression measured by a micro strain gauge attached to the diaphram, a strain gauge attached to the stomach or in the upper **duodenum** to measure gastro-intestinal motility and the type of motility, and a pressure transducer to measure the increase in biliary duct pressure, and use the combination of these signals to detect the injection of a narcotic; the dispensing pump may then release a narcotic antagonist and/or, for behavioral training, may release a drug that would cause nausea and vomiting, thus providing for behavioral modification or avoidance conditioning.

In relation to the other cited patents, Gray et al. shows in figure 5 an apparatus capable of performing the method steps disclosed in claim 1. Similarly, Orth et al., also discloses an apparatus capable of performing the method steps disclosed in claim 1. Accordingly, it is concluded that these cited patents anticipate the subject matter disclosed in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ellinwood, Jr., Garay et al, and Orth et al., in view of Burke et al.**

In order to clearly demonstrate the conventionality of using attachment means to fix implantable devices to body tissue, the examiner of record introduces Burke et al. This patent discloses the use of suture loops (36) to secure an implantable apparatus to body tissue. Based in the teachings of Burke et al., for a person of ordinary skill in the art, modifying any implantable device with suture loops in order to secure said implantable device to the body would have been considered obvious in view of the conventionality of the enhancement.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Petrakis and Casper et al., in view of Burke, et al.**

The Petrakis and Casper et al., patents disclose an implant comprising of a first portion having a shape memory polymer and a second portion having a pharmacologically active composition. These patents do not teach the use of attachment means to secure the implantable device to the body. However, as explained above, such attachment means are conventional in the art as evidenced by the teachings of Burke et al. Accordingly, modifying the implantable apparatuses disclosed by Petrakis and/or Casper et al., with attachment means would have been considered obvious in view of the conventionality of this particular enhancement.

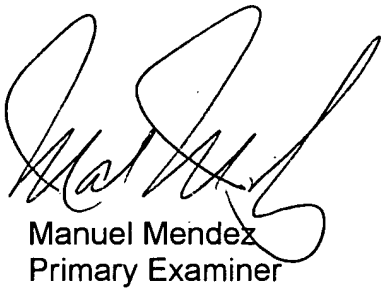
Claims 2-7 and 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ellinwood, Jr., Garay et al, and/or Orth et al., in view of Petrakis, Casper et al., and Burke, et al.**

The enhancements disclosed in the claims in question disclose limitations that are conventional in the art as evidenced by the teachings of Petrakis, Casper et al., and Burke, et al. Accordingly, for a person of ordinary skill in the art, the modification of the apparatuses disclosed by **Ellinwood, Jr., Garay et al, and/or Orth et al.,** with the use of shape memory polymers and attachment means would have been considered obvious in view of the teachings of **Petrakis, Casper et al., and Burke, et al.**, as discussed in the previous rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM